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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,545 ✓	05/07/2001 ✓	Kevin K. Liu	PC10777ABTC ✓	1324

7590 10/02/2002  
Gregg C. Benson  
Pfizer Inc.  
Patent Department, MS 4159  
Eastern Point Road  
Groton, CT 06340

EXAMINER

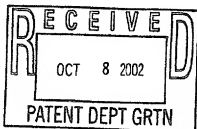
WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



→ Restriction Requirement due Nov 2, 2002  
→ Deadline six months - April 2, 2003

## Office Action Summary

Application No.  
09/850,545

Applicant(s)

Liu

Examiner  
Randall WinstonArt Unit  
1651

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s), \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s), \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a process for preparing a compound of the formula wherein the compound is prepared in the presence of a hydrolytic enzyme (lipase and/or esterase and/or liver acetone powder) and an aqueous buffer solution, classified in class 435, subclass 118, for example.

II. Claims 15-23, drawn to a process for preparing a compound of the formula wherein the compound is prepared in the presence of a lipase and an aqueous solution and (b) reacting the compound of formula IV with a base in the presence of a polar protic solvent, classified in class 514, subclass 576, for example.

III. Claims 24-33, drawn to a process for preparing a compound of the formula wherein the compound is prepared in the presence of a lipase and an acetylating agent and (b) reacting the compound of formula IV with a base in the presence of a polar solvent, classified in class 514, subclass 579, for example.

IV. Claims 34-40, drawn to a process for preparing a compound of the formula wherein the compound is prepared in the presence of a lipase, classified in class 514, subclass 428, for example.

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2. The inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These methods (i.e., Inventions I-IV are different methods of making in the presence of) are distinct since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. In addition, one would not have to practice the various methods at the same time to practice just one method alone.

3. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication should be directed to Randall Winston at telephone number (703) 305-0404. The examiner can normally be reached during the hours of 08:30 to 17:00 Eastern.

If attempts to reach the examiner by telephone are unsuccessful, a message may be left on the voice mail. The fax number the Art 1651 (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. My supervisor, Michael Wityshyn, may be contacted at (703) 308-4743.

Randall Winston  
Examiner, 1651



CHRISTOPHER R. TATE  
PRIMARY EXAMINER

✓  
RECORDABLE  
FILE COPY

Date Mailed: 11-1-02 Express Mail No. \_\_\_\_\_  
 Application No. 09/850,545 Docket No. PC10777A By els  
 Application of Kevin K. Liu  
 Entitled Enzymatic Resolution of Selective Estrogen Receptor Modulators

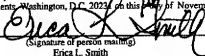
The following, due \_\_\_\_\_ in the U.S. Patent and Trademark Office, has been received there on the date stamped hereon:

- |  |   |
|--|---|
| <input type="checkbox"/> Specification _____ pages                                   | <input type="checkbox"/> Amendment  |
| <input type="checkbox"/> Claims _____ pages  | <input checked="" type="checkbox"/> Reply (1)                                       |
| <input type="checkbox"/> Abstract _____ pages  | <input type="checkbox"/> Notice of Appeal   |
| <input type="checkbox"/> Drawing(s) _____ sheets                                     | <input type="checkbox"/> Brief (3 copies)   |
| <input type="checkbox"/> Declaration with <input type="checkbox"/> Power of Attorney | <input type="checkbox"/> Petition for Extension of Time                             |
| <input type="checkbox"/> Assignment & Recordation Cover Sheet                        | <input type="checkbox"/> Filing of Missing Parts                                    |
| <input type="checkbox"/> Letter of Transmittal                                       | <input type="checkbox"/> Express Mail Certificate                                   |
| <input type="checkbox"/> Disclosure Statement _____ References                       | <input type="checkbox"/> Associate Power of Attorney                                |
| <input type="checkbox"/> Form PTO-FB-A820  | <input type="checkbox"/> Petition for Expedited Issuance for Foreign Filing License |
| <input type="checkbox"/> Issue Fee Transmittal                                       | <input type="checkbox"/> Provisional Cover Sheet                                    |
| <input type="checkbox"/> Fee Address Indication Form                                 | <input type="checkbox"/> PTO-1390 (DO/EQ/US) _____ pages                            |
| <input type="checkbox"/> Priority Document   | <input type="checkbox"/> Form PTO-1050  |
| <input type="checkbox"/> Cert. of Correction under 37 CFR 1.322(a)                   |   |
| <input type="checkbox"/> _____   | <input type="checkbox"/> _____  |

Attorney Docket No. PC10777A  
Application No. 09/850,545

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Hon. Commissioner for Patents, Washington, D.C. 20231, on this 11th day of November, 2002.

By



(Signature of person mailing)  
Erica L. Smith

(Typed or printed name of person)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Kevin K. Liu

Examiner: Randall O. Winston

Application No.: 09/850,545

Art Unit: 1324

Filing Date: May 7, 2001

Title: Enzymatic Resolution of  
Selective Estrogen Receptor Modulators

**Box Non-Fee Amendment**  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

**RESPONSE**

This is a response to the Official Action dated October 2, 2002, which contained only a Restriction Requirement.

**Remarks**

Applicants have been required to elect a Group of claims for prosecution.

Applicants hereby elect to prosecute the claims of Group I, claims 1-14

Consideration and allowance of claims 1-14 is respectfully requested.

Date: 11/1/2002

By:



Todd M. Crissey  
Registration No. 37,807

Pfizer Inc.  
Patent Department, MS: 8260-1611  
Eastern Point Road  
Groton, CT 06340  
Phone: (860) 715-4331  
Fax: (860) 441-5221

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Art Unit: 1654

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#### DETAILED ACTION

#### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue of fee.

Authorization for this examiner's amendment was given in a telephone interview with John Wichtowski on Dec 3, 2003.

#### IN THE CLAIMS

Claims 15-40 have been canceled. Applicant reserves the right to file one or more divisional applications regarding the subject matter of the canceled claims.

In claim 1,

the phrase "in the presence of a hydrolytic enzyme and an aqueous buffer solution." has been omitted and replaced with the following phrase:

--

in the presence of an aqueous buffer solution and a hydrolytic enzyme selected from the group consisting of lipase, esterase, and liver acetone powder.

--

In claim 14,

the phrase "in the presence of a hydrolytic enzyme and an aqueous buffer solution." has been omitted and replaced with the following phrase:



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--

in the presence of an aqueous buffer solution and a hydrolytic enzyme selected from the group consisting of lipase, esterase, and liver acetone powder.

--

Claims 1-14 are allowable.

***Reasons for Allowance***

The following is an examiner's statement of the reasons for allowance: A process for preparing the recited chemical compound via the instantly claimed method including using a hydrolytic enzyme selected from the group consisting of lipase, esterase, and liver acetone powder within the claimed deacetylating step is neither taught nor reasonably suggested by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.



CHRISTOPHER R. TATE  
PRIMARY EXAMINER

**Ex Parte Reexamination Interview Summary**

Control No.

09/850,545

Patent Under Reexamination

LIU, KEVIN K.

Examiner

RANDALL WINSTON

Art Unit

1654

All participants (USPTO personnel, patent owner, patent owner's representative):

(1) RANDALL WINSTON

(3) \_\_\_\_\_

(2) John Wichtowski

(4) \_\_\_\_\_

Date of Interview: 03 December 2003Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal (copy given to: 1) ☐ patent owner 2) ☐ patent owner's representative)Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.  
Any other agreement(s) are set forth below under "Description of the general nature of what was agreed to..."Claim(s) discussed: 1-40

Identification of prior art discussed: \_\_\_\_\_

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:  
Applicant's representative, John Wichtowski has replaced former Applicant's representative Todd Crissey. John Wichtowski has given examiner Randall Winston authorization to cancel claims 15-40 and to allow claims 1-14 according to the examiner's amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims patentable, if available, must be attached. Also, where no copy of the amendments that would render the claims patentable is available, a summary thereof must be attached.)

A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION MUST INCLUDE PATENT OWNER'S STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. (See MPEP § 2281). IF A RESPONSE TO THE LAST OFFICE ACTION HAS ALREADY BEEN FILED, THEN PATENT OWNER IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO PROVIDE THE MANDATORY STATEMENT OF THE SUBSTANCE OF THE INTERVIEW (37 CFR 1.560(b)). THE REQUIREMENT FOR PATENT OWNER'S STATEMENT CAN NOT BE WAIVED. EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).

cc: Requester (if third party requester)

Examiner's signature, if required



Conforms with FORM PTO-FB-A820

## INFORMATION DISCLOSURE